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PACESETTER, INC.
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EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	**PAPER NUMBER**
3762	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,847	ER, SIEW	
	Examiner	Art Unit	
	Christopher A. Flory	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 26-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 26-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-10 and 26-30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mulligan et al. (US Patent 6,438,408 hereinafter Mulligan'408).

Regarding claims 1-3, 9, Mulligan'408 discloses a method of recording information related to procedures performed by a care provider during a follow-up consultation with a patient having an implanted device (Fig. 4; column 1, lines 15-22), analyzing the procedures; recommending one or more procedures for a subsequent follow-up consultation (column 9, lines 19-37; column 17, lines 12-42); and presenting information indicative of a recommended sequence of procedures for follow-up (column 16, lines 5-67). Mulligan'408 clearly discloses several instances of sequential information or sequential steps to be undertaken. In column 16, lines 5-67, Mulligan'408 discloses that parameters are determined periodically throughout each day (i.e. sequentially). Additionally, in those same lines, Mulligan'408 discloses that the physician may advise the patient to undertake certain activities at precise times of the day or to initiate determination of parameters using a programmer. This is effectually an output from the physician, indicative to the patient, presenting information of a recommended sequence of procedures for a subsequent follow-up consultation. While

Mulligan'408 does not expressly disclose that the recording and analysis of information be carried out exclusively between the external programmer and implanted device but rather includes input, analysis and recommendation of follow-up procedure by a physician, it would have been obvious to one of ordinary skill in the art at the time of the invention to use an external programmer to perform and store these steps, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

Further regarding claim 1, the steps of the claimed method can be repeated for any number of patients by any number of care providers. Mere repetition of steps or methods is not enough to patentably distinguish over the prior art.

Regarding claim 4, Mulligan'408 discloses the recording of threshold assessments (column 10, lines 26-48; column 24, lines 48-53).

Regarding claims 5 and 8, Mulligan'408 discloses recording rhythm assessments (column 17, lines 54-62; column 8, lines 36-61). This inherently involves pattern analysis, since a rhythm is a cyclically recurring pattern.

Regarding claim 6, statistical analysis is an inherent component of analyzing data whether performed by a computational device or a human user. Any device that records multiple data points and assesses these points to output a recommended procedure must inherently perform analysis, and therefore statistical analysis, of that data. Similarly, a human user who reads raw data points and comes to a conclusion

based on those data points, has performed statistical analysis. (See also column 12, lines 44-67).

Regarding claim 7, a confidence level (or confidence interval) is synonymous with "margin of error" analysis, and can be defined as a range on either side of a mean or predetermined value for which a criterion is considered to be successfully met. For example, if event X is considered to occur at an average reading of 12V with a confidence interval of 1 volt, then a recording Y of 12.6V is read as a successful event X. Mulligan'408 discloses a method of recording parameters when the heart rate is in a normal range and stable within a certain stability tolerance programmed by the physician or determined over a series of heart cycles (column 17, line 64 through column 18, line 25). In the language of the example, event X is the normal heart rate, mean value is that value determined over a series of heart cycles and predetermined value is that programmed by the physician. The confidence interval is synonymous with the stability tolerance. Event Y is each calculated heart rate. This is a clear disclosure of confidence level analysis, and as such the instant application does not distinguish over the prior art.

Regarding claims 10, the method of Mulligan'408 inherently involves using guidelines, because guidelines are requisite for any meaningful analysis of data.

Regarding claim 26, Mulligan'408 shows a device (Fig. 2) with a means for recording procedures (column 6, lines 1-8; IMD memory); a means for analyzing the procedures (Fig. 2, microcomputer 102 and input signal processing circuit 108); statistical analysis software (column 12, lines 44-67); and a means for recommending

one or more procedures (telemetry transceiver 124 and antenna 28); wherein recording procedures occur in real time (column 14, lines 24-52).

Regarding claim 27, Mulligan'408 discloses storing the presented information in the external programmer (column 14, lines 24-52).

Regarding claims 28-30, any information gathered, stored, and transmitted by a device implanted in a patient and in some way used or interpreted by a physician, care giver, or even in instances where the patient herself has control on implant parameters; can be considered to correspond to any of the care provider, patient, or implanted device. Since Mulligan'408 discloses such a scenario, it is considered to expressly or inherently disclose the limitations of these claims.

3. Claims 1-6, 9, 10 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell (US Patent 6,405,087, hereinafter Snell'087).

Snell'087 clearly discloses the method and apparatus of the instant application substantially as claimed in the ABSTRACT as well as Figures 1 and 2 and column 8, lines 16-30. Snell'087 does not expressly disclose that the recording and analysis of information be carried out exclusively between the external programmer and implanted device but rather includes input, analysis and recommendation of follow-up procedure by a physician. It would have been obvious to one of ordinary skill in the art at the time of the invention to use an external programmer to perform and store these steps, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

Regarding claims 28-30, any information gathered, stored, and transmitted by a device implanted in a patient and in some way used or interpreted by a physician, care giver, or even in instances where the patient herself has control on implant parameters; can be considered to correspond to any of the care provider, patient, or implanted device. Since Snell'087 discloses such a scenario, it is considered to expressly or inherently disclose the limitations of these claims.

4. Claims 1-3, 5, 6, 8-10 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malek et al. (US Patent Publication 2003/0171789, hereinafter Malek'789).

Regarding claims 1-3, Malek'789 discloses a method of recording information related to procedures performed by a care provider (physician) during a follow-up consultation with a patient having an implanted device, interrogating the implanted device for diagnostic data, analyzing the procedures, and recommending one or more procedures for a subsequent follow-up consultation (paragraphs [6] and [7], [35], and [50]-[52]), wherein the one or more procedures inherently contains a sequence of steps or procedures. While Malek'789 does not expressly disclose that the recording and analysis of information be carried out exclusively between the external programmer and implanted device but rather includes input, analysis and recommendation of follow-up procedure by a physician, it would have been obvious to one of ordinary skill in the art at the time of the invention to use an external programmer to perform and store these steps, since it has been held that broadly providing a mechanical or automatic means to

replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

It is noted that the screening phase is considered the first consultation such that the implant phase is the follow-up consultation. During the implant phase, the physician analyzes the data collected during the screening phase and adjusts parameters as needed to provide effective care to the patient, which is considered the recommending of procedures through physical reprogramming of the implanted device. It is further noted that the patient has a programmer that can be used to adjust the implanted device at their own discretion, and that the patient may also be considered a care provider.

Regarding claims 5 and 8, Malek'789 discloses a device that may be used for circadian rhythm linked therapies (paragraph [46]). This inherently involves pattern analysis, because the circadian rhythm is a cyclically recurring pattern of approximately 30 days.

Regarding claim 6, statistical analysis is an inherent component of analyzing data whether performed by a computational device or a human user. Any device that records multiple data points and assesses these points to output a recommended procedure must inherently perform analysis, and therefore statistical analysis, of that data. Similarly, a human user who reads raw data points and comes to a conclusion based on those data points, has performed statistical analysis.

Regarding claim 9, the method of Malek'789 involves comparing procedural information of the implant phase with the previously recorded procedural information of

the screening phase. Inherently, one cannot make a comparison without having a previously recorded set of data with which to compare a current set of data.

Regarding claims 10, the method of Malek'789 inherently involves using guidelines, because guidelines are requisite for any meaningful analysis of data.

Regarding claim 26, Malek'789 discloses a device (Fig. 5C, physician programmer 310; Figure 6, patient programmer 320) with a means for recording procedures (memory 640); a means for analyzing the procedures (microcontroller 510 and microprocessor 620); and a means for recommending one or more procedures (telemetry unit 630 in figure 6; telemetry port, IR port, and input displays and buttons in Figure 5); further comprising a means for communicating with the implanted device (telemetry unit 620); wherein recording procedures occur in real time (Fig. 5, real time clock). The Malek'789 device is considered to perform statistical analysis based on the disclosure of monitoring circadian rhythm therapies (paragraph [46]). Any computational device that performs statistical analysis must inherently contain statistical analysis software in order for the system to function properly. Therefore, the instant application does not distinguish over the Malek'789 device.

Regarding claims 28-30, any information gathered, stored, and transmitted by a device implanted in a patient and in some way used or interpreted by a physician, care giver, or even in instances where the patient herself has control on implant parameters; can be considered to correspond to any of the care provider, patient, or implanted device. Since Snell'087 discloses such a scenario, it is considered to expressly or inherently disclose the limitations of these claims.

5. Claims 1-5, 10 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al. (US Patent 7,136,707, hereinafter Hall'707).

Hall'707 clearly discloses the method and apparatus of the instant application substantially as claimed in the ABSTRACT as well as Figures 2-4; 2, lines 39-61; column 3, lines 3-24; and column 4, lines 1-15. Hall'707 does not expressly disclose that the recording and analysis of information be carried out exclusively between the external programmer and implanted device but rather includes input, analysis and recommendation of follow-up procedure by a physician and partial automation using the external device (column 3, lines 19-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to use an external programmer to perform and store these steps, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

Regarding claim 29, Hall'707 discloses that the information corresponds to the patient (column 3, lines 8-10).

Regarding claim 30, Hall'707 discloses that the information corresponds to the type of implanted device (column 3, lines 5-8 and 13-16).

Regarding claim 28, any information gathered, stored, and transmitted by a device implanted in a patient and in some way used or interpreted by a physician, care giver, or even in instances where the patient herself has control on implant parameters; can be considered to correspond to the care provider.

Response to Arguments

6. Applicant's arguments filed 16 May 2007 have been fully considered but they are not persuasive.

7. Claims 1-10 and 26-30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mulligan'408.

It is noted that the Applicant's primary arguments regard the fact that the analysis and recommendation of follow-up procedures in the Mulligan'408 reference are performed by a physician rather than an external programmer. It would have been obvious to one of ordinary skill in the art at the time of the invention to use an external programmer to perform and store these steps, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

Additionally, Applicant argues that Mulligan'408 records parameter data such as blood pressure and that such data does not correspond to "recorded information" as claimed by the Applicant, which includes the sequence in which procedures are performed between an external and internal device. It is noted that, while physiological data does not directly disclose a sequence of steps carried out, it is nonetheless data *related to* the procedures carried out between the external and internal device, since the physiological data is transmitted between the two, and additionally must be transmitted in a sequence, such a transmission constituting the procedure being carried out.

Additionally, Applicant points to column 16, lines 5-67, stating that the physician recommends to a patient to undertake certain activities at precise times (a sequence of steps carried out there beteween) and to initiate the internal device using a programmer at specific times, again seen as a procedure related to the external device (either the physician or the patient) and the internal device. Therefore, the automation of the manual means is taken to read on the claim limitations.

Regarding the limitation of "repeating" steps in claim 1, a mere repetition of steps, or reiteration of a process, is considered to be an obvious variation of the step or process in its singular instance, as it merely constitutes performing the previously disclosed process more than once.

8. Claims 1-6, 9, 10 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell'087. Regarding Snell'087, Applicant argues that Snell'087 records performance data rather than information related to the procedures performed between the external programming system and the implanted device. Similar to the case with Mulligan'408,, while physiological data does not directly disclose a sequence of steps carried out, it is nonetheless data *related to* the procedures carried out between the external and internal device, since the physiological data is transmitted between the two, and additionally must be transmitted in a sequence, such a transmission constituting the procedure being carried out.

9. Claims 1-3, 5, 6, 8-10 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malek'789. Regarding Malek'789, Applicant again argues that only parameter settings, patient diagnostic data, device usage data, data regarding the last

session between the programmer and the external system, etc. For the same reasons as above, it is nonetheless data *related to* the procedures carried out between the external and internal device, since the physiological data is transmitted between the two, and additionally must be transmitted in a sequence, such a transmission constituting the procedure being carried out. Alternatively, one could see the type of data recorded in Malek'789 to be the sequence of steps carried out between the external device and the implant, and therefore is related to the procedures performed therebetween because they *are* the procedures carried out therebetween. In paragraph 52, Malek'789 discloses that the stored settings in the implant can be changed through the programmer, again constituting recorded data related to procedures performed between external and internal device components.

10. Claims 1-5, 10 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al. (US Patent 7,136,707, hereinafter Hall'707). Regarding Hall'707, it is again noted that a mere repetition of steps, or reiteration of a process, is considered to be an obvious variation of the step or process in its singular instance, as it merely constitutes performing the previously disclosed process more than once. Therefore performing the procedure over several follow-up consultations rather than one follow-up is not considered to distinguish over the Hall'707 reference.

11. Applicant's arguments, see paragraph 1 of page 14, filed 16 May 2007, with respect to claims 6-9 as rejected by Hall'707 have been fully considered and are persuasive. The Hall'707 rejection of claims 6-9 has been withdrawn.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

1 October 2007

/George Manuel/
Primary Examiner